

WHAT IS CLAIMED IS AS FOLLOWS:

1. A medical device comprising:
a catheter comprising a proximal portion, a distal portion, a shaft and an expandable member located at the distal portion, said expandable member being
5 constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state; and
protector means comprising a removable sleeve positioned around the expandable member, said sleeve comprising a first end and a second end and having a variable inner diameter.
- 10 2. The medical device of claim 1 wherein the expandable member comprises a balloon and the distal portion further comprises at least one dam.
3. The medical device of claim 1 wherein the sleeve comprises a straight tube.
4. The medical device of claim 3 wherein at least a portion of the sleeve is dimpled.
5. The medical device of claim 3 wherein the entire sleeve is dimpled.
- 15 6. The medical device of claim 4 wherein the dimples are round-like.
7. The medical device of claim 4 wherein the dimples are helical grooves.
8. The medical device of claim 1 wherein the first end of the sleeve further comprises a proximal flare.
9. The medical device of claim 1 wherein said sleeve has a slit extending
20 therethrough.
10. The medical device of claim 9 wherein the slit is a longitudinal slit extending from the first end of the sleeve to the second end of the sleeve.
11. The medical device of claim 9 wherein the slit is a spiral slit extending in a helical manner from the first end of the sleeve to the second end of the sleeve.
- 25 12. The medical device of claim 9 wherein the slit extends distally in a helical manner from the first end of the sleeve and defines a proximal spiral region, said sleeve further comprising a distal continuous tubular portion.
13. The medical device of claim 12 wherein the distal continuous tubular portion further comprises a dimpled region and a substantially smooth region.
- 30 14. The medical device of claim 13 wherein the dimples are round-like.
15. The medical device of claim 13 wherein the dimples are helical grooves.

16. The medical device of claim 12 wherein the first end of the sleeve further comprises a proximal flare.

17. A medical device comprising:

5 a catheter comprising a proximal portion, a distal portion, a shaft and an expandable member located at the distal portion, said expandable member being constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state; and

removable protector means comprising:

10 a first removable inner sleeve positioned around the expandable member, said sleeve comprising a first end and a second end and having a variable inner diameter;

a second removable outer sleeve positioned over the first sleeve, said second sleeve having a first end and a second end, said first and second sleeves being removed prior to use of the medical device.

15 18. The medical device of claim 17 wherein the expandable member and the first sleeve are of a material which resiliently deforms under radial pressure.

19. The medical device of claim 17 wherein the first sleeve and the second sleeve are made of a low friction material.

20. The medical device of claim 17 wherein said first sleeve is coextruded and has a 20 high friction inner diameter and a low friction outer diameter, whereby the inner sleeve will not slip when the outer sleeve is pushed thereon.

21. The medical device of claim 17 wherein at least one of said first and second sleeves is a straight or continuous tube.

22. The stent delivery system of claim 21 wherein at least a portion of said at least 25 one continuous tube is dimpled.

23. The medical device of claim 22 wherein the continuous tube has round-like dimples.

24. The medical device of claim 22 wherein the continuous tube has helical grooved dimples.

30 25. The stent delivery system of claim 22 wherein the entire continuous tube is dimpled.

00413131400

26. The medical device of claim 17 wherein at least one of said first and second sleeves has a slit extending therethrough.

27. The medical device of claim 26 wherein the slit is a longitudinal slit extending from the first end of the sleeve to the second end of the sleeve.

5 28. The medical device of claim 26 wherein the slit is a spiral slit extending in a helical manner from the first end of the sleeve to the second end of the sleeve.

29. The medical device of claim 26 wherein the slit extends distally in a helical manner from the first end of the sleeve and defines a proximal spiral region, said sleeve further comprising a distal continuous tubular portion.

10 30. The medical device of claim 29 wherein the distal continuous tubular portion further comprises a dimpled region and a substantially smooth region.

31. The medical device of claim 30 wherein the dimples are round-like.

32. The medical device of claim 30 wherein the dimples are helical grooves.

33. The medical device of claim 17 wherein the distal portion of the catheter further
15 comprises at least one enlarged portion, whereby when compressed by the outer sleeve, the inner sleeve will have an inner diameter less than or equal to the outer diameter of the at least one enlarged portion.

34. The medical device of claim 33 wherein the at least one enlarged portion
20 comprises a proximal dam and a distal dam spaced a predetermined distance apart, said dams having an equal outer diameter, and the expandable member comprises a balloon located over and between said dams.

35. A stent delivery system comprising:

25 a catheter comprising a proximal portion, a distal portion, a shaft and an expandable member located at the distal portion, said expandable member having a first end and a second end and being constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state;

30 a radially expandable stent of generally cylindrical configuration positioned around said distal portion of said catheter around the expandable member, said stent having a contracted condition, being sized in the contracted condition to closely surround the catheter in the contracted state, and further being expandable to an expanded condition;

removable stent protector means comprising a first removable sleeve in the region of the distal portion of the catheter positioned around the stent, said first sleeve further comprising a first end, and a second end, said first sleeve having a variable inner diameter to ease sliding the first sleeve over the balloon and stent, said stent protector means being removed prior to use of the stent delivery system and release of the stent by expansion of the balloon.

36. The stent delivery system of claim 35 wherein the expandable member and the first sleeve are of a material which resiliently deforms under radial pressure.

37. The stent delivery system of claim 35 wherein the stent is crimped to the expandable member for delivery.

38. The stent delivery system of claim 35 wherein the first sleeve is made of a low friction material.

39. The stent delivery system of claim 35 wherein the first sleeve has a lubricious coating thereon.

40. The stent delivery system of claim 35 wherein the first sleeve is a straight continuous tube.

41. The medical device of claim 40 wherein at least a portion of the continuous tube is dimpled.

42. The medical device of claim 41 wherein the continuous tube has round-like dimples.

43. The medical device of claim 41 wherein the continuous tube has helical grooved dimples.

44. The medical device of claim 41 wherein the entire continuous tube is dimpled.

45. The stent delivery system of claim 35 wherein the first end of the first sleeve further comprises a proximal flare.

46. The stent delivery system of claim 35 wherein said first sleeve has a slit extending therethrough.

47. The stent delivery system of claim 46 wherein the slit is a longitudinal slit extending from the first end of the sleeve to the second end of the sleeve.

48. The stent delivery system of claim 46 wherein the slit is a spiral slit extending in a helical manner from the first end of the sleeve to the second end of the sleeve.

09718-13400

49. The medical device of claim 46 wherein the slit extends distally in a helical manner from the first end of the sleeve and defines a proximal spiral region, said sleeve further comprising a distal continuous tubular portion.

50. The medical device of claim 49 wherein the distal continuous tubular portion further comprises a dimpled region and a substantially smooth region.

51. The medical device of claim 50 wherein the dimples are round-like.

52. The medical device of claim 50 wherein the dimples are helical grooves.

53. The stent delivery system of claim 35 wherein the stent protector means further comprises a second removable sleeve having a first end and a second end, said second sleeve being positioned over the first sleeve and having a constrictive relationship with said first sleeve.

54. The stent delivery system of claim 53 wherein the distal portion of the catheter further comprises at least one dam, over which the expandable member extends, and wherein when the first sleeve is compressed by the second (outer) sleeve, the first sleeve has an inner diameter less than or equal to the outer profile of the expandable member over the at least one dam.

55. The stent delivery system of claim 54 wherein said at least one dam comprises a proximal dam and a distal dam spaced a predetermined distance apart, said dams having an equal outer diameter, the expandable member is a balloon located over and between said proximal and distal dam, the stent is located over the balloon and between the dams and the first sleeve has a length approximately equal to that of the stent.

56. The stent delivery system of claim 53 wherein the first sleeve and the second sleeve are made of a low friction material.

57. The stent delivery system of claim 53 wherein said first sleeve is coextruded and has a high friction inner diameter and a low friction outer diameter, whereby the first sleeve will not slip when the second sleeve is pushed thereon.

58. The stent delivery system of claim 53 wherein at least one of said first sleeve and second sleeve is a continuous tube.

59. The stent delivery system of claim 58 wherein at least a portion of said at least one continuous tube is dimpled.

60. The stent delivery system of claim 59 wherein the entire continuous tube is

0073719-121400

dimpled.

61. The stent delivery system of claim 59 wherein the dimples are round-like.

62. The stent delivery system of claim 59 wherein the dimples are helical grooves.

63. The stent delivery system of claim 59 having round-like dimples and helical
5 dimples.

64. The stent delivery system of claim 58 wherein said at least one straight tube further comprises a proximal flare.

65. The stent delivery system of claim 53 wherein at least one of said first and second sleeves has a slit extending therethrough.

10 66. The stent delivery system of claim 65 wherein the slit is a longitudinal slit extending from the first end of the sleeve to the second end of the sleeve.

67. The stent delivery system of claim 65 wherein the slit is a spiral slit extending in a helical manner from the first end of the sleeve to the second end of the sleeve.

68. The stent delivery system of claim 65 wherein the slit extends distally in a
15 helical manner from the first end of the sleeve and defines a proximal spiral region, said sleeve further comprising a distal continuous tubular portion.

69. The stent delivery system of claim 68 wherein at least a portion of the distal continuous tubular portion further comprises a dimpled region.

70. The stent delivery system of claim 69 wherein the dimpled region has round-like
20 dimples.

71. The stent delivery system of claim 69 wherein the dimpled region has dimpled helical grooves.

72. The stent delivery system of claim 53 wherein the expandable member comprises a balloon made of an elastomeric material.

25 73. The stent delivery system of claim 53 wherein the first sleeve further comprises removal means extending from the second end thereof, said removal means comprising a tail.

74. A system for intraluminal delivery of a stent comprising: a balloon catheter comprising a shaft, a balloon associated with a distal portion of the shaft for receiving a
30 stent, the shaft further comprising at least one dam and an inflation lumen associated with the balloon for inflation thereof; stent retaining means comprising a first removable

0973718-131400

sleeve for positioning around a stent and a second removable sleeve for positioning around the first sleeve such that the first sleeve is compressed by the second sleeve to an inner diameter less than or equal to the outer diameter of the at least one dams, said first and second sleeves being removed prior to use of the delivery system and release of a stent mounted to the catheter for delivery thereof by expansion of the balloon.

75. The system of claim 74 wherein the distal portion of the catheter comprises a proximal dam and a distal dam spaced a predetermined distance apart, said dams having an equal outer diameter, the balloon portion is located over and between the dams, and the stent is located over the balloon and between the dams.

76. The system of claim 74 wherein: the first sleeve is made of a lubricious material and further comprises a first end, a second end and a slit extending therethrough, said slit providing a variable inner diameter to ease sliding the first sleeve over a stent mounted on the balloon; and the second sleeve has an inner diameter, prior to mounting on the catheter, less than the outer diameter of the first sleeve prior to mounting on the catheter.

77. The system of claim 76 wherein the slit is a longitudinal slit.

78. The system of claim 76 wherein the slit is in a spiral configuration.

79. The system of claim 76 wherein the slit extends distally in a helical manner from the first end of the sleeve and defines a proximal spiral region, said sleeve further comprising a distal continuous tubular portion.

80. The system of claim 79 wherein at least a portion of distal continuous tubular portion is dimpled.

81. The system of claim 80 wherein said dimpled portion has round-like dimples.

82. The system of claim 80 wherein said dimpled portion has dimpled helical grooves.

83. The system of claim 76 wherein one of said first and second sleeves comprises a coiled flat wire, spring wound without a gap between the coils thereof.

84. The system of claim 76 wherein at least one of said sleeves comprises a polymeric tube having a first end, a second end, and a variable inner diameter, wherein at least one of said ends is flared, said tube having a slit extending from the first end to the second end, enabling said sleeve to be peeled off the catheter.